

# TYGON® ND Series

The Next Generation  
of Non-DEHP Tubing  
for the Medical Device Market



## Global Presence, Local Resource



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TYGON® is a registered trademark.

Saint-Gobain Non-DEHP tubing contains DEHP levels of <1000 ppm.

**IMPORTANT:** It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics tubing for all intended uses. Laboratory and clinical tests must be conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of tubing in any particular application.

For a period of 6 months from the date of first sale, Saint-Gobain Performance Plastics Corporation warrants this product to be free from defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. THIS WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized.

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[www.medical.saint-gobain.com](http://www.medical.saint-gobain.com)

Saint-Gobain is the world's leading producer of engineered, high-performance polymer products. Our core competency lies in our process technologies — technologies that transform difficult-to-process materials into useful products for industry. These materials include fluoropolymers (PTFE, PFA and FEP), silicone rubber and a range of other high-performance engineered polymers. Our tradition of excellence goes back more than 300 years through our parent company, Compagnie de Saint-Gobain, one of the world's top 100 industrial corporations, with operations in more than 60 countries. We leverage our global technology to provide worldwide advanced materials research, polymer processing and manufacturing support unmatched by any competitor.

**Important:** "This Saint-Gobain product is a medical component intended for processing or use in the manufacture or assembly of medical devices before the finished medical device is packaged/labeled; it is intended to be included as part of the finished, packaged, and labeled device [21CFR820.3(c)]. Please refer to our Medical Products Disclaimer at [www.medical.saint-gobain.com/resources/regulatory-and-quality/medical-product-disclaimer](http://www.medical.saint-gobain.com/resources/regulatory-and-quality/medical-product-disclaimer).

**Caution:** For manufacturing, processing or repacking"

Saint-Gobain, a world leader in the development of higher performance polymer products, offers a new alternative to DEHP-plasticized PVC.

### Medical Grade Vinyl Tubing Products

From typical applications such as blood and IV bags to enteral feeding, ECMO and dialysis tubing, polyvinyl chloride (PVC) is widely used throughout the healthcare industry. However, ongoing studies of di (2-ethylhexyl) ester (DEHP), a phthalate plasticizer commonly used in flexible PVC products, have raised concerns regarding its use in medical applications. In response to these changing needs, the Saint-Gobain R&D team has formulated a complete range of non-DEHP plasticized materials that meet DEHP performance criteria for critical attributes including clarity, flexibility, chemical resistance, bondability and shelf life.

### Biocompatibility

TYGON® ND Series tubing products were developed specifically for use in medical applications. All formulations meet the requirement of the USP <88>, Plastics Class VI. Additionally, the ND 100-65 material carries a full complement of biocompatibility testing, including pyrogenics, hemolytics and toxicity.

### EU MDR and REACH compliance for DEHP

Based upon a unique chemistry developed by Saint-Gobain, TYGON® ND Series tubing was formulated to be compliant with Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and to Regulation (EU) 2017/745 on medical devices (EU MDR) for DEHP. To ensure compliance, every individual compound lot is tested to ensure DEHP levels are <1000 ppm. During the extrusion process, individual product dimensions are maintained and monitored through in-line micrometers and off-line verification with computerized imaging equipment.

### Typical Applications

- Dialysis equipment
- Minimally invasive devices
- Peristaltic pumps
- Inhalation equipment
- Medical laboratories
- Blood and IV solutions



### TYGON® ND 100 Series Plasticizer: TOTM

Shelf Life: 3 years

Product	Durometer Hardness, Shore A, 15 sec	Color	Tensile Strength, psi (MPa)	Ultimate Elongation, %	Tear Resistance lb f/in (kN/m)	Specific Gravity	Water Absorption, % 24 hrs. @23°C	Compression Set Constant Deflection, % @ 158°F (70°C) for 22 hours
ASTM Method	D2240	–	D412	D412	D1004	D792	D570	D395
ND 100-40	40	Clear	1225 (8.4)	380	70 (12.3)	1.13	0.17	53
ND 100-55	55	Clear	1725 (11.9)	425	145 (25.4)	1.18	0.14	57
ND 100-65	65	Clear	2075 (14.3)	415	185 (32.4)	1.19	0.12	60
ND 100-70	70	Clear	2300 (15.90)	415	210 (36.8)	1.19	0.12	60
ND 100-80	80	Clear	2625 (18.1)	350	275 (48.2)	1.21	0.12	59
ND 100-40 replaces TYGON® S-40-HL / ND 100-65 replaces TYGON® S-50-HL / ND 100-80 replaces TYGON® S-54-HL								

### TYGON® ND 200 Series Plasticizer: DINCH

Shelf Life: 3 years

Product	Durometer Hardness, Shore A, 15 sec	Color	Tensile Strength, psi (MPa)	Ultimate Elongation, %	Tear Resistance lb f/in (kN/m)	Specific Gravity	Water Absorption, % 24 hrs. @23°C	Compression Set Constant Deflection, % @ 158°F (70°C) for 22 hours
ASTM Method	D2240	–	D412	D412	D1004	D792	D570	D395
ND 200-40	40	Clear	1125 (7.8)	370	60 (10.5)	1.09	0.20	49
ND 200-55	55	Clear	1625 (11.2)	385	120 (21.0)	1.14	0.16	52
ND 200-65	65	Clear	2000 (13.8)	385	155 (27.1)	1.17	0.15	57

### TYGON® ND 300 Series Plasticizer: DOA

Shelf Life: 1 year

Product	Durometer Hardness, Shore A, 15 sec	Color	Tensile Strength, psi (MPa)	Ultimate Elongation, %	Tear Resistance lb f/in (kN/m)	Specific Gravity	Water Absorption, % 24 hrs. @23°C	Compression Set Constant Deflection, % @ 158°F (70°C) for 22 hours
ASTM Method	D2240	–	D412	D412	D1004	D792	D570	D395
ND 300-40	40	Clear	1075 (7.4)	435	55 (9.6)	1.10	0.29	55
ND 300-55	55	Clear	1575 (10.9)	435	100 (17.5)	1.14	0.24	60
ND 300-65	65	Clear	1900 (13.1)	415	155 (27.1)	1.16	0.24	59

Shore A Hardness was measured on 1/4 in. buttons  
Unless otherwise noted, all tests were conducted at room temperature (73°F). Values shown were determined on 0.075" thick molded ASTM plaques or molded ASTM durometer buttons.